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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,270	01/02/2004	Marvin A. Genshaw	MSE #2672	1737

7590 08/09/2006

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EXAMINER	
SUAREZ, FELIX E	

ART UNIT	PAPER NUMBER
2857	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,270	GENSHAW, MARVIN A.	
	Examiner	Art Unit	
	Felix E. Suarez	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11-39 and 41-46* is/are rejected.

7)☒ Claim(s) *7-10 and 40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *28February2006*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Withdrawal of Finality of Last Office Action

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6, 11-39 and 41-46 rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al. (U.S. Patent No. 5,856,195) in view of Heller et al. [U.S. Patent No. 6,560,471].

With respect to claims 1 and 39, Charlton et al. (hereafter Charlton) teaches a test device (or system) for determining the concentration of an analyte in a sample, the test device having a memory in which a plurality of calibration adjustments corresponding to a plurality of calibration numbers are stored, the test device being adapted to receive a test sensor for collecting the sample, the test sensor containing a reagent adapted to produce a reaction indicative of the

concentration of the analyte in the body fluid, the test sensor having an associated calibration number of a plurality of digits, the device comprising:

a measuring unit for measuring the reaction of the reagent and the analyte and for generating a signal indicative of the measured reaction (see col. 1, lines 15-35; col. 13, lines 31-36 and col. 14, lines 42-44);

Charlton does not teach, a single calibration input element for permitting a user to input the calibration number, one digit at a time, associated with the test sensor.

But Heller et al. (hereafter Heller) teaches in an analyte monitoring device that, a transmitter, an optional receiver may be included in the on-skin sensor control unit. In some cases, the transmitter is a transceiver, operating as both a transmitter and a receiver. The receiver may be used to receive calibration data for the sensor. The calibration data may be used by the processing circuit to correct signals from the sensor. This calibration data may be transmitted by the receiver/display unit or from some other source such as a control unit in a doctor's office (see Heller; col. 49, lines 55-63).

Heller also teaches that, alternative or additional calibration data may be provided based on tests performed by a doctor or some other professional or by the patient himself. For example, it is common for diabetic individuals to determine their own blood glucose concentration using commercially available testing kits. The results of this test is input into the on-skin sensor control unit either directly, if an appropriate input device (e.g., a keypad, an optical signal

receiver, or a port for connection to a keypad or computer) is incorporated in the on-skin sensor control unit, or indirectly by inputting the calibration data into the receiver/display unit, and transmitting the calibration data to the on-skin sensor control unit (see Heller; col. 50, lines 12-24).

Heller further teaches that, the processing circuit of the on-skin sensor control unit and/or an analyzer of the receiver/display unit, may determine when calibration data is needed and if the calibration data is acceptable (see Heller; col. 50, lines 54-59).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Charlton to include a receiver/display unit as taught by Heller, because the receiver/display unit of Heller allows to input calibration data by a patient himself and the calibration input data may be a digit or two digits depending the calibration data needed or acceptable according with a range, rate, maximum or minimum threshold (see Heller col. 50 line 57 to col. 51 line12), as desired.

Charlton further teaches, a processor electronically coupled to the single calibration input element and the measuring unit, the processor being adapted to determine the concentration of the analyte in the sample in response to receiving the inputted calibration number and receiving the signal indicative of the measured reaction from the measuring unit (see col. 4, lines 1-18 and col. 4, lines 42-47); and

a user display electronically coupled to the processor for displaying digits to be selected from by a user inputting the calibration number and for displaying the determined concentration of the analyte in the sample (see col. 3, lines 26-30 and FIG. 1).

With respect to claim 2, Charlton further teaches that, the calibration number includes a first digit and a second digit (see col. 6, lines 26-33), the processor being adapted to commence scrolling through a plurality of numbers on the user display (see col. 4, lines 42-60), from which the first digit of the calibration number is selected, upon activation of the single calibration input element by the user, the processor being adapted to suspend scrolling through the numbers upon deactivation of the single calibration input element by the user, the processor accepting the number displayed on the user display at the time of the deactivation of the single calibration input element as the first digit of the calibration number (see col. 11, lines 38-62).

With respect to claims 3, 24, 28 and 46, Charlton further teaches that, the processor accepts the displayed number after a predetermined time period measured from the deactivation of the single calibration input element (see col. 3, lines 32-47 and col. 11, lines 51-62).

With respect to claim 4, Charlton further teaches that, the processor is adapted to commence scrolling through a plurality of numbers on the user display, from which the second digit of the calibration number is selected, upon activation of the single calibration input element by the user after acceptance by the processor of the first digit of the calibration number, the processor being adapted to suspend scrolling through the numbers upon deactivation of the single calibration input element by the user, the processor accepting the number displayed on the user display at the time of the deactivation of the single calibration input element as the second digit of the calibration number (see col. 6, lines 26-33 and col.11, lines 38-62).

With respect to claims 5 and 41, Charlton further teaches that, the processor prompts the user, via the display, to input a first digit of the calibration number (see col. 6, lines 8-18 and col. 11, lines 18-25).

With respect to claim 6, Charlton further teaches that, the processor is adapted to scroll through a plurality of numbers on the user display, from which the first digit of the calibration number is selected, in response to a plurality of activations of the single calibration input element by the user, the processor accepting a displayed number as the first digit of the calibration number after a predetermined time measured from a most-recent activation of the single calibration input element (see col. 4, lines 52-65 and col. 11, lines 38-50).

With respect to claim 11, Charlton further teaches that, the calibration number consists of a predetermined number of digits, the processor adjusting the at least one adjustable parameter of the concentration equation according to the stored adjustment corresponding to the input calibration number upon receipt of each of the predetermined number of digits of the calibration number (see col. 11, lines 51-62).

With respect to claims 12, 25 and 29, Charlton further teaches comprising an enter input element, the processor accepting the inputted calibration number upon receipt user input, via the enter input element, indicating that each of the plurality of digits of the predetermined number have been input (see col. 11, lines 18-37).

With respect to claims 13, 31 and 42, Charlton further teaches that, the calibration number ranges between two digits and five digits (see col. 6, lines 61-63 and col. 8, lines 29-36).

With respect to claims 14, 26, 30, 32 and 43, Charlton further teaches that, the calibration number has a number base selected from the group consisting of number base three, number base four, number base five, and number base six (see col. 9, lines 31-35 and col. 10, lines 31-36).

With respect to claim 15, Charlton further teaches that, the processor is adapted to display on the user display a previously entered calibration number upon an initial activation of the single calibration input element (see col. 3, lines 32-47).

With respect to claims 16 and 33, Charlton further teaches that, the reagent is adapted to produce an optical reaction and the measuring unit is adapted to measure the optical reaction (see col. 4, lines 16-18).

With respect to claims 17 and 34, Charlton further teaches that, the optical reaction is a colorimetric reaction and the measuring unit is adapted to measure the colorimetric reaction (see col. 4, lines 16-18 and col. 1, lines 15-26).

With respect to claims 18 and 35, Charlton further teaches that, the reagent is adapted to produce an electrochemical reaction and the measuring unit is adapted to measure the electrochemical reaction (see col. 4, lines 16-18 and col. 1, lines 15-26).

With respect to claims 19 and 36, Charlton further teaches that, the sample is blood (see col. 4, lines 39-56).

With respect to claims 20 and 37, Charlton further teaches that, the analyte is glucose (see col. 4, lines 39-56).

With respect to claim 22, Charlton teaches a method for entering a multiple-digit calibration number into a test device, the test device having a memory in which a plurality of calibration adjustments corresponding to a plurality of calibration numbers are stored, the test device being adapted to receive a test sensor for collecting a sample, the test sensor containing a reagent adapted to produce a reaction indicative of the concentration of the analyte in the sample, the test sensor having an associated calibration number, the method comprising:

measuring the reaction of between an analyte in a collected body fluid sample and the reagent contained in the test sensor (see col. 4, lines 44-56);

determining the concentration of the analyte in the body fluid in response to receiving the calibration number from the user and measuring the reaction (see col. 13. lines 31-36 and col. 1, lines 10-35);

displaying the determined concentration of the analyte in the body fluid on the user display (see col. 3, lines 32-47 and col. 4, lines 52-60).

Charlton does not teach, prompting a user, via a user display, to enter a digit of the calibration number; nor

receiving input from the user, via a single calibration input element, indicative of the calibration number, one digit at a time.

But Heller et al. (hereafter Heller) teaches in an analyte monitoring device that, a transmitter, an optional receiver may be included in the on-skin sensor control unit. In some cases, the transmitter is a transceiver, operating as both a transmitter and a receiver. The receiver may be used to receive calibration data for the sensor. The calibration data may be used by the processing circuit to correct signals from the sensor. This calibration data may be transmitted by the receiver/display unit or from some other source such as a control unit in a doctor's office (see Heller; col. 49, lines 55-63).

Heller also teaches that, alternative or additional calibration data may be provided based on tests performed by a doctor or some other professional or by the patient himself. For example, it is common for diabetic individuals to determine their own blood glucose concentration using commercially available testing kits. The results of this test is input into the on-skin sensor control unit either directly, if an appropriate input device (e.g., a keypad, an optical signal receiver, or a port for connection to a keypad or computer) is incorporated in the on-skin sensor control unit, or indirectly by inputting the calibration data into the receiver/display unit, and transmitting the calibration data to the on-skin sensor control unit (see Heller; col. 50, lines 12-24).

Heller further teaches that, the processing circuit of the on-skin sensor control unit and/or an analyzer of the receiver/display unit, may determine when calibration data is needed and if the calibration data is acceptable (see Heller; col. 50, lines 54-59).

Heller also teaches that, the on-skin sensor control unit and/or receiver/ display unit may include an auditory or visual indicator that calibration data is needed, based, for example, on a predetermined periodic time interval between calibrations or on the implantation of a new sensor (see Heller; col. 50, lines 42-53)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Charlton to include a receiver/display unit as taught by Heller, because the receiver/display unit of Heller allows to display a visual indicator indicating that calibration data is needed and the receiver/display unit of Heller allows to input calibration data by a patient himself and the calibration input data may be a digit or two digits depending the calibration data needed or acceptable according with a range, rate, maximum or minimum threshold (see Heller col. 50 line 57 to col. 51 line12), as desired.

With respect to claims 23 and 27, Charlton further teaches that, receiving input from the user indicative of the calibration number further comprises:

(a) prompting the user to input a particular one of the multiple digits of the calibration number (see col. 4, lines 52-60) ;

(b) scrolling through a plurality of digits, one at a time, from which the particular one of the multiple digits can be selected, on the user display in response to repeated activations of the single calibration input element by the

user until a displayed number is displayed on the user display (see col. 6, lines 22-33);

(c) accepting the displayed number as the particular one of the multiple-digits of the calibration number (see col. 6, lines 46-48); and

(d) repeating (a) through (c) until all of the digits of the multiple-digit calibration number have been accepted (see col. 4, lines 56-59).

With respect to claim 38, Charlton further teaches that, determining comprises determining the concentration of the analyte in the sample according to a calibration equation having an adjustable parameter and adjusting the adjustable parameter according to the stored adjustment corresponding to the inputted calibration number (see col. 11, lines 38-62).

With respect to claim 45, Charlton further teaches that, the processor is adapted to display on the user display a previously entered calibration number upon an initial activation of the single calibration input element (see col. 3, lines 32-47 and col. 11, lines 18-25).

Allowable Subject Matter

3. Claims 7-10 and 40, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. The following is a statement of reasons for the indication of allowable subject matter:

Claims 7-10, would be allowable over the prior art for at least the reason that the prior art fail to teach or suggest that:

the processor prompts the user, via the display, to input a second digit of the calibration number upon acceptance of the first digit.

Claim 40 would be allowable over the prior art for at least the reason that the prior art fail to teach or suggest that:

the processor is adapted to receive a calibration number of a specific number of digits, the processor permitting a user to scroll through an array of numbers being displayed on the user display, one number at a time, such that the next number in the array of numbers to be displayed is displayed in response to each activation of the single calibration input element, each digit of the calibration number being selected from the array of numbers, the processor accepting a displayed number as the particular digit of the calibration number presently being inputted by the user in response to not receiving input from the single calibration input element for a predetermined time period, the processor entering the accepted numbers as the calibration number upon acceptance of a number as a last number of the specific number of digits.

Response to Arguments

5. This action is responsive to papers filed 03/17/2006.

6. Applicant's arguments with respect to the claims have been fully considered but they are moot in view of the new ground(s) of rejection set forth hereinbefore.

Conclusion

Prior Art

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Douglas et al. [U.S. Patent No. 6,106,780] describes an intelligent calibration device.

Douglas et al. [U.S. Patent No. 6,750,962] describes an optics alignment and calibration system.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Felix Suarez, whose telephone number is (571) 272-2223. The examiner can normally be reached on weekdays from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc Hoff can be reached on (571) 272-2216. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications.

August 4, 2006

F.S.

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